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TAN-285 PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re the application of

Hideki UMEYAMA and Naomi NAKAKI

Serial No.: 09/834,886 Group: 3712

Filed: April 16, 2001 Examiner: K. FERNSTROM

For: A MODEL FOR TRAINING SURGICAL OPERATION OF CATARACT

The Honorable Commissioner of
Patents and Trademarks
Washington, D.C. 20231

RECEIVED JUL 28 2003 TECHNOLOGY CENTER R3700

DECLARATION

Sir:

I, Nomi Nakaki, do hereby declare and state as follows:

I am a citizen of Japan with a residence at 2-19-105, Higashi-shinmachi, Ikoma-shi, Nara-ken, Japan.

I am one of the inventors of the subject matter of this application and am familiar with the Office Action on April 24, 2003 and all of the references cited therein.

In 1986, I graduated from the faculty of Medicine of Osaka Municipal University and was employed as an eye surgical doctor of the attached hospital of the University. And the main subject of my study was the surgical operation of cataract.

In 1993, I established Oji Station Eye Clinic and am continuing the study and experiment of surgical operation of cataract up to the present time.

I declare, the training of surgical operation of cataract recorded in the video tape which I submit as the evidence of the present invention is showing the training process

using the pig's eye model for training of surgical operation of cataract of the present invention. As clearly demonstrated in the videotape, the method using the model of the present invention is to incise the anterior capsule as the first step, then whole lens is removed. The gelling agent is injected into the emptied lens capsule. Therefore, the obtained nucleus is consisting of the hardened subject of said gelling agents and not the denatured product of the originated lens protein. Since the hardness of this artificial nucleus is changeable, the same action such as planing or cracking to the nucleus of cataract of human can be carried out at the operation. The hardness of nucleus of the present invention is similar to that of actual nucleus of cataract, and differs from the soft one which can be fabricated using formalin. Concerning the extraction of the nucleus, in the model prepared by injecting formalin in lens, only small denatured protein locating at the center part is removed. While, in the case of gelling agent injecting method of the present invention, whole contents of the lens capsule becomes false nucleus. According to the prior art, since a lens protein is hardened by the action of formalin, the visual field in an anterior capsule becomes cloudy.

I declare, the most important point of the present invention is to use the empty lens capsule of pig's eye as a bag and the gelling agent is filled up into the bag and to fabricate a new nucleus. That is, the exist of the lens protein is not necessary and the desired false nucleus can be fabricated. Further, the training of enucleating operation to enucleate a fallen nucleus lens by an operation error from the corpus vitreum becomes possible using the training model of the present invention. And these points are the unexpected effects of the present invention.

I declare further that all statements made herein of my own knowledge are true and that all statements made on information and believed to be true; and further that these statements and the like so made are punishable for fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application or any patent thereon.

Date 2nd day of June, 2003 Signature 中木直美

Naomi Nakaki

APPENDIX B

<Concerning Simulated Cataract Produced on a Butchered Pig's Eye with Gelling Agent>

I: Difference in the Conception

The conceptions in producing simulated cataract on a butchered pig's eye totally differ between that of Dr. Sugiura's team and Dr. Nakaki's team.

II: Simplicity in Actual Experiments

Since Dr. Sugiura's method uses formalin and alcohol on the market, it is relatively easy to experiment. On the other hand, Dr. Nakaki's pig's eye requires a special gelling reagent for its production and therefore lacks of simplicity and convenience for the experiment.

III: Handling Care of the Reagents

Due to its chemical nature, the formalin contained in Dr. Sugiura's pig's eye requires care in its handling during the experiment and also when it is to be discarded. Whereas the ingredients of the gelling reagent of Dr. Nakaki's are mainly polyvalent alcohol, so it is safer and easier to handle and can be discarded as harmless wastes.

IV: Difference in the two Doctors' Pig's Eyes

In Dr. Sugiura's pig's eye, the above mentioned chemicals are used to degenerate the protein in the lens, so the size and hardness of the produced simulated cataract relies upon the degree of degeneration of the protein that originally existed in the lenticular bag.

With Dr. Nakaki's pig's eye, however, the lenticular bag is merely used as a container, and the protein in the lens is discarded. Therefore, the size and the hardness of the simulated cataract can be altered by adjusting the property and amount of the gelling reagent for various purposes. In addition, a variety of colored cataracts can be produced with different coloring matters.

V: Similarity to Human Cataract Operation

The process of producing Dr. Nakaki's pig's eyes is very much like the actual operation of phacoemulsification, therefore this method is of great value in learning the techniques required in human cataract operations.

July 15th, 2003

Takeshi Sugiura, MD